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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,577	03/21/2005	Ulrich Speck	WEICKM-44	8523

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EXAMINER	
BOUCHELLE, LAURA A	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
08/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,577	SPECK ET AL.	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46,49 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/3/09 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The term "during stent implantation" in claim 49 is a relative term which renders the claim indefinite. The term "during stent implantation" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The period of time required to implant a stent is not definite and changes from patient to patient and practitioner to practitioner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-9, 14, 15-20, 22-29, 37-42, 44-46, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates et al (US 2004/0073284) in view of Dror et al (US 5102402). Bates discloses a coated medical device comprising a lipophilic drug adhered to the surface of a medical device; the drug is released immediately upon contact with the tissue. The drug is carried on a balloon 26 having longitudinal folds 46, 48, 50 (Page 10, paragraph 0092). See Fig. 7. The drug may be paclitaxel (Page 2, paragraph 0014). The device may or may not include a stent.

7. Regarding claim 6, Bates discloses that only a part of the balloon may be coated (page 10, paragraph 0097).

8. Regarding claims 15, 38, Bates discloses that the drug is in suspension that is sprayed on to the device in an ethanol solution (Page 8, paragraph 0068). The device of Bates may be used to treat vascular disease (paragraph 003) or a tumor (paragraph 0055).

9. Regarding claim 24, Bates discloses that paclitaxel may be sprayed on the surface of the base material in a concentration of 5 ug/mm^2 (Page 8, paragraph 0068). The example cited by Bates states that the base material is a stent, but one of skill in the art would recognize that this is an example and when taken in whole, it is clear that Bates intends the coating to be used on either a balloon, a stent, or a balloon and stent together. Furthermore, Bates discloses that when using paclitaxel , the drug need only contact the target area for a very short time to provide lasting effects (page 11, paragraph 0100) and therefore one of skill in the art would recognize that a balloon which contacts the treatment site for a short time can be as effective as a stent

which remains at the site for a longer time period so the concentration used for both the balloon and the stent would be similar.

10. Regarding claim 50, the limitation "a short time" is interpreted to be any length of time from an instant to a number of minutes or even hours.

11. Claims 1, 24, 50 differ from Bates in calling for the drug to be adhered to a smooth surface of the balloon. Dror teaches a balloon having a drug coating. The drug coating may be contained within the surface texture of the balloon in a similar manner to that of Bates, or may be attached to a smooth surface of the balloon by an adhesive (col. 5, lines 40-53). Regarding claim 4, Dror teaches that the drug remains adhered to the balloon after the balloon is folder where it remains until deployment of the balloon (Col. 5, lines 10-11). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates to have a drug coating on a smooth surface as taught by Dror because Dror teaches that a drug can be coated on either a smooth or textured surface, both methods providing good adhesion and delivery of the drug to the intended target tissue.

12. Claims 10, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Dror in view of Desai et al (US 5916596).

13. Claims 10, 30 call for the drug to include amorphous structures with particle sizes ranging from 0.1 to 5 microns. Bates teaches that the drug is a quick dissolving lipophilic drug such as paclitaxel but fails to disclose the particle size. Desai teaches that it is known in the art to use paclitaxel particles having a diameter of less than one micron so that the drug can be delivered in vivo. See Abstract. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates to have the drug in particles of

less than about one micron as taught by Desai so that the drug can be delivered in vivo regardless of its water solubility.

14. Claims 11-13, 31, 32, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Dror in view of Barry et al (US 6306166).

15. Claims 11-13, 31, 32, 36 differ from Bates in calling for the drug to be embedded in a readily water-soluble matrix, the matrix to be a low molecular weight hydrophilic substance. Barry teaches loading and release of water insoluble drugs such as paclitaxel in a low molecular weight matrix that allows the drug to be adhered to a medical device and still be absorbed into the tissue (Col. 15, lines 16-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates to have the drug embedded in a low molecular weight matrix as taught by Barry so that the drug can have good adhesion to the medical device and be readily absorbed by the tissue.

16. Claims 21, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Dror in view of Ding et al (US 6364856).

17. Claims 21, 43 differ from Bates in calling for the device to be sterilized using ethylene oxide. Ding teaches a medical device with a coating for controlled drug release similar to that of Bates, but further including the step of sterilizing the device using ethylene oxide as is well known in the art (Col. 6, lines 57-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Bates to include the step of sterilizing the device using ethylene oxide as taught by Ding because it is well known that

devices to be inserted into a patient need to be sterilized and using ethylene oxide is an established technique for sterilization of medical devices.

18. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates in view of Dror in view of Barry as applied to claim 31 above, and further in view of Klaveness et al (US 6177061).

19. Claims 33-35 differ from the teachings above in calling for the matrix to be a contrast agent, and the contrast agent is iopromide. Klaveness teaches the use of iopromide in a matrix material so that the matrix can be visualized when it is inside the body using x-ray (Col. 7, lines 14-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bates in view of Barry so that the matrix is formed of the contrast agent iopromide as taught by Klaveness so that the substance can be visualized using x-ray.

Response to Arguments

20. Applicant's arguments filed 6/3/09 have been fully considered but they are not persuasive. Applicant argues that Bates does not teach the concentration of the drug on the surface to be up to ug/mm^2. The examiner disagrees. The example cited by Bates states that the base material is a stent, but one of skill in the art would recognize that this is an example and when taken in whole, it is clear that Bates intends the coating to be applied to either a balloon, a stent, or a balloon and stent together (page 3, paragraph 0015). Furthermore, Bates discloses that when using paclitaxel , the drug need only contact the target area for a very short time to provide lasting effects (page 11, paragraph 0100). Given this teaching, one of skill in the art would

recognize that a balloon which contacts the treatment site for a short time can be as effective as a stent which remains at the site for a longer time period so the concentration used for both the balloon and the stent would be similar.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
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